**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING  
REJECTION OVER A "PRIOR" PATENT**Docket Number (Optional)  
019941-000620USIn re Application of: Atushi Kajiyama, *et al.*

Application No.: 10/667,077

Filed: September 18, 2003

For: QUICK DISINTEGRATING TABLET IN BUCCAL CAVITY AND MANUFACTURING METHOD THEREOF

The owner\*, Yamanouchi Pharmaceutical Co., Ltd., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term of **prior patent** No. 6,656,492 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☒ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☐ The undersigned is an attorney or agent of record. Reg. No. \_\_\_\_\_

Signature

January 5, 2006

Date

Yuji Watanabe, Vice-President of Intellectual Property, Astellas

Typed or printed name

Pharma, Inc.

81 3 3244 3375

Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

\*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).  
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

60640069 v1

\* Name change documents for Assignee are attached hereto.

01/19/2006 DENMANU1 00000024 201430 10667077

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**STATEMENT UNDER 37 CFR 3.73(b)**Applicant/Patent Owner: Atushi KaiiyamaApplication No./Patent No.: 10/667,077 Filed/Issue Date: September 18, 2003Entitled: QUICK DISINTEGRATING TABLET IN BUCCAL CAVITY AND MANUFACTURING METHOD THEREOFYamanouchi Pharmaceutical Co., Ltd., a Assignee  
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.  
The extent (by percentage) of its ownership interest is \_\_\_\_\_ %

in the patent application/patent identified above by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 012448, Frame 0458, or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

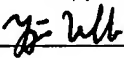
1. From: \_\_\_\_\_ To : \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
2. From: \_\_\_\_\_ To : \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
3. From: \_\_\_\_\_ To : \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

- ☒ Copies of assignments or other documents in the chain of title are attached.

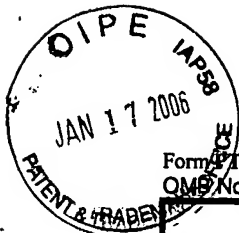
[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

 January 5, 2006  
Signature Date

Yuji Watanabe, Vice-President, Intellectual Property, 81 2 3244 3375  
Printed or Typed Name Astellas Pharma Inc. Telephone Number

\_\_\_\_\_  
Title



Form **PTO-1595** (Rev. 03/05)  
OMB No. 0651-0027 (exp. 6/30/2005)

Attorney Docket No. 019941-000110US

U.S. DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office

## RECORDATION FORM COVER SHEET PATENTS ONLY

To the Director of the U.S. Patent and Trademark Office: Please record the attached documents or the new address(es) below.

### 1. Name of conveying party(ies)

Yamanouchi Pharmaceutical Co., Ltd.

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

### 3. Nature of conveyance/Execution Date(s):

Execution Date(s) April 1, 2005

- ☐ Assignment ☒ Merger  
☐ Security Agreement ☒ Change of Name  
☐ Joint Research Agreement  
☐ Government Interest Assignment  
☐ Executive Order 9424, Confirmatory License  
☐ Other \_\_\_\_\_

### 2. Name and address of receiving party(ies)

Name: Astellas Pharma Inc.

Internal Address: \_\_\_\_\_

Street Address: 3-11, Nihonbashi-Honcho  
2-chome, Chuo-Ku

City: Tokyo

State: \_\_\_\_\_

Country: Japan Zip: 103-8411

Additional name(s) & address(es) attached? ☐ Yes ☒ No

### 4. Application or patent number(s):

☐ This document is being filed together with a new application.

#### A. Patent Application No.(s)

10/866524

09/834410

#### B. Patent No.(s)

6368629

6506407

Additional numbers attached? ☒ Yes ☐ No

### 5. Name and address to whom correspondence concerning document should be mailed:

Name: Joseph R. Snyder

Internal Address: \_\_\_\_\_

TOWNSEND AND TOWNSEND AND CREW LLP

Street Address: Two Embarcadero Center,  
Eighth Floor

City: San Francisco

State: California Zip: 94111-3834

Phone Number: (925) 472-5000

Fax Number: (415) 576-0300

Email Address: js@townsend.com

### 6. Total number of applications and patents involved: 55 (Fifty-five)

### 7. Total fee (37 CFR 1.21(h) & 3.41) \$ 2200.00

- ☐ Authorized to be charged by credit card  
☒ Authorized to be charged to deposit account  
☐ Enclosed  
☐ None required (government interest not affecting title)

### 8. Payment Information

a. Credit Card Last 4 numbers \_\_\_\_\_  
Expiration Date \_\_\_\_\_

b. Deposit Account Number 20-1430

Authorized User Name Townsend and

Townsend and Crew LLP

### 9. Signature: Joseph R. Snyder

Signature

December 13, 2005

Date

Joseph R. Snyder

Name of Person Signing Atty. Reg. No. 39,381

Total number of pages including cover sheet, attachments, and documents:

38

571-273-0140

1. Additional name(s) of conveying party(ies):  
(Continued from Page 1)
2. Additional name(s) and address(es) of receiving party(ies):  
(Continued from Page 1)
3. Additional application number(s) or patent number(s):  
(Continued from Page 1)

A. Patent Application No.(s)

10/667077

09/907557

10/949114

11/009644

10/206010

10/345051

10/393766

10/672398

10/674581

10/754341

10/766201

10/746562

10/975210

10/842809

10/843005

11/119460

60/714924

60/701139

11/105938

11/105668

11/105665

60/147222

60/197574

60/198086

60/215292

60/218980

60/257652

60/290300

60/308303

60/349784

60/365752

60/365697

60/414313

60/415026

60/439560

60/442984

60/453046

60/515070

60/567301

60/561990

60/562149

60/562019

60/562035

PCT/US05/12837

B. Patent No.(s)

6562375

6656492

6761895

6872405

6328979

6919372

6589554

Astellas Pharma Inc.

Company number 0199-01-034966

3-11, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo

## Certificate of All the Records Registered

Trade name	<u>Yamanouchi Pharmaceutical Co., Ltd.</u>	
	Astellas Pharma Inc.	Changed April 1, 2005
		Registered April 1, 2005
Location of head office	3-11, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo	
Method of public notice	The statement is executed by publication in the <i>Nihon Keizai Shimbun</i> issued in Tokyo.	
Matters necessary for obtaining information relating to the balance sheet	<a href="http://www.yamanouchi.com/jp/index.html">http://www.yamanouchi.com/jp/index.html</a>	Established March 25, 2003
		Registered April 1, 2003
	<a href="http://www.astellas.com/jp">http://www.astellas.com/jp</a>	Changed April 1, 2005
		Registered April 1, 2005
Date of incorporation	March 20, 1939	
Object	<ol style="list-style-type: none"> <li><u>1. Manufacture, sale, import and export of pharmaceuticals, quasi-drugs, drugs used for animals, industrial chemicals, agricultural chemicals and other chemical products</u></li> <li><u>2. Manufacture, sale, import and export of foods, food additives, seasonings, livestock feeds, feed additives, cosmetics, sanitary fixtures, medical instruments, meters and gauges, daily necessities and miscellaneous goods</u></li> <li><u>3. Manufacture, sale, import and export of medical machines and equipment, industrial machines and equipment and household equipment</u></li> <li><u>4. Manufacture, sale, import and export of alcoholic beverages and other beverages</u></li> <li><u>5. Breeding, sale, import and export of laboratory animals</u></li> <li><u>6. Sale, purchase, lease, and management of real estate and agency business thereof</u></li> <li><u>7. Warehouse business and road transport business</u></li> <li><u>8. Hotel business, and management and control of health and physical education facilities and equipment</u></li> <li><u>9. Casualty insurance agency business</u></li> <li><u>10. Information processing service business using computer</u></li> <li><u>11. All businesses incidental to or related to one of the preceding Items</u></li> </ol> <ol style="list-style-type: none"> <li>1. Manufacture, sale, import and export of pharmaceuticals, quasi-drugs, drugs used for animals, reagents, industrial chemicals, agricultural chemicals and other chemical products</li> <li>2. Manufacture, sale, import and export of foods, food additives, seasonings, fertilizers, livestock feeds, feed additives, cosmetics, sanitary fixtures, medical instruments, medical instruments used for animals, meters and gauges, daily necessities and miscellaneous goods</li> <li>3. Sale, purchase, import and export of natural products</li> <li>4. Lease and maintenance of medical instruments</li> <li>5. Manufacture, sale, import, export, lease and maintenance of medical machines and equipment, industrial machines and equipment and household equipment</li> <li>6. Scientific inspections related to medical treatment</li> <li>7. Manufacture, sale, import and export of liquors, alcoholic beverages and other beverages</li> <li>8. Breeding, sale, import and export of laboratory animals</li> <li>9. Sale, purchase, lease, and management of real estate and agency business thereof</li> <li>10. Warehouse business, road transport business and freight transport business</li> </ol>	



UNITED STATES  
PATENT AND  
TRADEMARK OFFICE



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JS  
019941-000610US

MARCH 06, 2002

TOWNSEND AND TOWNSEND AND CREW LLP  
JOSEPH R. SNYDER  
TWO EMBARCADERO CENTER, 8TH FLOOR  
SAN FRANCISCO, CA 94111-3834

Chief Information Officer  
Washington, DC 20231  
www.uspto.gov



\*101946168A\*

UNITED STATES PATENT AND TRADEMARK OFFICE  
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 01/07/2002

REEL/FRAME: 012448/0458

NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

KAJIYAMA, ATUSHI

DOC DATE: 10/17/2001

ASSIGNOR:

TAMURA, TETSUYA

DOC DATE: 10/17/2001

ASSIGNOR:

MIZUMOTO, TAKAO

DOC DATE: 10/17/2001

ASSIGNOR:

KAWAI, HITOSHI

DOC DATE: 10/17/2001

ASSIGNOR:

TAKAHASHI, TATSUYA

DOC DATE: 10/17/2001

ASSIGNEE:

YAMANOUCHI PHARMACEUTICAL CO.,  
LTD.

3-11 NIHONBASHI-HONCHO 2-CHOME,  
CHUO-KU  
TOKYO 103-8411, JAPAN

012448/0458 PAGE 2

SERIAL NUMBER: 09896820  
PATENT NUMBER:

FILING DATE: 06/28/2001  
ISSUE DATE:

MARY BENTON, EXAMINER  
ASSIGNMENT DIVISION  
OFFICE OF PUBLIC RECORDS

**ASSIGNMENT OF PATENT APPLICATION**

**JOINT**

WHEREAS, Atushi Kajiyama of 382-3, Gokahorinouchi, Yaizu-shi, Shizuoka, 425-0077, Japan; Tetsuya Tamura of 2-8, Maejima 2-chome, Fujieda-shi, Shizuoka, 426-0067, Japan; Takao Mizumoto of 457-2, Sumiyoshi, Yoshida-cho, Haibara-gun, Shizuoka, 421-0301, Japan; Hitoshi Kawai of 180-1, Ozumi, Yaizu-shi, Shizuoka, 425-0072, Japan; Tatsuya Takahashi of 1500-2 Sangamyou, Yaizu-shi, Shizuoka, 425-0071, Japan; hereinafter referred to as "Assignors," are the inventors of the invention described and set forth in the below-identified application for United States Letters Patent:

Title of Invention:      **QUICK DISINTEGRATING TABLET IN BUCCAL  
CAVITY AND MANUFACTURING METHOD  
THEREOF**

Date(s) of execution of Declaration:      **October 17, 2001**

Filing Date:              **June 28, 2001**

Application No.:          **09/896,820; and**

WHEREAS, Yamanouchi Pharmaceutical Co., Ltd., located at 3-11 Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo 103-8411, hereinafter referred to as "ASSIGNEE," is desirous of acquiring an interest in the invention and application and in any U.S. Letters Patent and Registrations which may be granted on the same;

For good and valuable consideration, receipt of which is hereby acknowledged by Assignors, Assignors have assigned, and by these presents do assign to Assignee all right, title and interest in and to the invention and application and to all foreign counterparts (including patent, utility model and industrial designs), and in and to any Letters Patent and Registrations which may hereafter be granted on the same in the United States and all countries throughout the world, and to claim the priority from the application as provided by the Paris Convention. The right, title and interest is to be held and enjoyed by Assignee and Assignee's successors and assigns as fully and exclusively as it would have been held and enjoyed by Assignors had this Assignment not been made, for the full term of any Letters Patent and Registrations which may be granted thereon, or of any division, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof.

Assignors further agree that they will, without charge to Assignee, but at Assignee's expense, (a) cooperate with Assignee in the prosecution of U.S. Patent applications and foreign counterparts on the invention and any improvements, (b) execute, verify, acknowledge and deliver all such further papers, including patent applications and instruments of transfer, and (c) perform such other acts as Assignee lawfully may request to obtain or maintain Letters Patent and Registrations for the invention and improvements in any and all countries, and to vest title thereto in Assignee, or Assignee's successors and assigns.



Assignors hereby authorize and request Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8<sup>th</sup> Floor, San Francisco, CA 94111-3834, to insert herein above the application number and filing date of said application when known.

IN TESTIMONY WHEREOF, Assignors have signed their names on the dates indicated.

Dated: October 17, 2001

Atushi Kajiyama  
Atushi Kajiyama

Dated: October 17, 2001

Tetsuya Tamura  
Tetsuya Tamura

Dated: October 17, 2001

Takao Mizumoto  
Takao Mizumoto

Dated: October 17, 2001

Hitoshi Kawai  
Hitoshi Kawai

Dated: October 17, 2001

Tatsuya Takahashi  
Tatsuya Takahashi